

K090474

510(k) SUMMARY
(as required by 807.92(e))

OCT 19 2009

Regulatory Correspondent: Regulatory and Marketing Services, Inc.
962 Allegro Lane
Apollo Beach, FL 33572
Jon Ward
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Submitter of 510(k): Orthosensor, Inc.
1560 Sawgrass Corporate Pkwy, 4th Floor
Sunrise, FL 33323
Mark Stein
Phone: 954-577-7770
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Date of Summary: September 27, 2009

Trade/Proprietary Name: OrthoRex Intra-Operative Load Sensor

Classification Name: Intraoperative orthopedic joint assessment aid

Product Code: ONN

Intended Use: For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The force sensor is sterile, for single patient use.

Device Description: Orthosensor Intra-Operative Load Sensor (IOLS) system provides a means to dynamically balance the knee during knee replacement surgery intra-operatively. The system includes an instrumented trial tibial insert comprising an array of load sensors that measure the forces applied on its surface after insertion into the space between the tibia and the femur.

Predicate Device: Elibra Dynamic Knee Balancer – K070108

Substantial Equivalence: The Orthosensor, Inc. claims the proposed device to be substantially equivalent to the device previously cleared by FDA in K070108. Orthosensor, Inc. claims this equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles, and physical, operational specifications as compared to the predicate devices.

The similarities and differences between the proposed and predicate devices have been identified and explained in the Substantial Equivalence Discussion which has been included in Section 10 of this submission. These differences identified have no impact on safety or effectiveness.

Performance Testing: The proposed device has undergone a series of bench testing which includes mechanical, engineering, and comparison studies. The results of the testing have shown the device to perform in accordance with internal and customer requirements and the device performance has not shown any negative impact on the safety and effectiveness of the proposed device when compared to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Orthosensor, Inc.
% Mr. Jon Ward
Regulatory and Marketing Services, Inc.
962 Allegro Lane
Apollo Beach, Florida 33572

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2009

Re: K090474

Trade/Device Name: OrthoRex Intra-Operative Load Sensor
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: ONN
Dated: August 9, 2009
Received: August 13, 2009

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

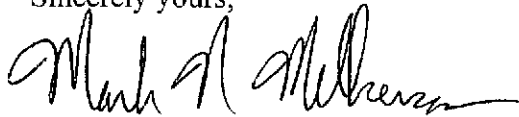
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", written in a cursive style.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: OrthoRex Intra-Operative Load Sensor

Indications for Use: For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The force sensor is sterile, for single patient use


Prescription Use Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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